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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,623	04/30/2001	Sudhir Agrawal	47508.528	2601

32254 7590 12/23/2002

KEOWN & ASSOCIATES  
500 WEST CUMMINGS PARK  
SUITE 1200  
WOBURN, MA 01801

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/23/2002

123

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/845,623

Applicant(s)

AGRAWAL ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 & 8.                      6) ☐ Other: \_\_\_\_\_

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***Detailed Action***

The Group and/or Art Unit of the U.S. Patent application SN 09/845,623 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to the Technology Center 1600, Art Unit 1623.

***Election/Restrictions***

Claims 1-22 are pending in the instant application.

Applicant's election without traverse of Group IV, claims 18-22, in Paper No. 11 is acknowledged. Claims 1-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

An action on the merits of claims 18-22 is contained herein.

***Amendments***

Acknowledgment is made of receipt of preliminary amendment filed August 13, 2001, Paper No. 4, and paragraphs 1-3 on page 6 have been replaced by substitute paragraphs.

Acknowledgment is made of receipt of amendment filed November 6, 2002, Paper No. 11, and original claim number 18 has been amended.

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***Priority***

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e) to provisional application number 60/201,578 filed May 1, 2000.

***Information Disclosure Statement***

Acknowledgement is made to applicant's submittal of Information Disclosure Statements filed September 14, 2001 and July 16, 2002, paper numbers 6 and 8 respectfully, and the references, except for the A12 (Crooke) reference which was not provided, have been taken into consideration in the instant application.

***Specification***

The specification is objected to wherein the specification recites on page 7, lines 3-5, "The patents and publications cited herein reflect the level of knowledge in the filed and are hereby incorporated by reference in their entirety." Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973).

Applicant is required to delete above "incorporation by reference" recitation, or amend specification wherein particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.

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### ***Claim Objections***

Claim 18 is objected to because of the following informalities: exhibit B submitted in the amendment filed November 6, 2002, Paper No. 11 contains an underscore ( ) between “wherein” and “the” in line 5 and additionally exhibit A and exhibit B both recite “consisting of guanosime” in line 4. A corrected copy of exhibit A and B is respectfully requested. It is noted that in an effort to provide compact prosecution, the claim has been interpreted as being drawn to “consisting of guanosine” and containing no underscore between “wherein the”.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ The term "similar" in claim 18 is a relative term which renders the claim indefinite. The term "similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Lacking specificity of how “similar” a compound must be, leaves uncertainty as to what applicant intends their invention to encompass. Clarity is respectfully requested.

✓ Claim 21 recites the limitation "wherein the compounds" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 21, and claim 18

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from which it depends, are drawn to administering a compound, methods drawn to administering a plurality of compounds lacks antecedent basis. Clarity is respectfully requested.

Claim 22 is rejected wherein the claim recites “wherein dosage of compound is from about **0.1 mg per patient per day to about 200 mg per kg body weight per day**”. The designated dosage range provides conflicting units of measure which in combination are inconsistent with conventional dosage regimens, which normally provide ranges which contain equivalent units of measure for the high end and low end of the range. Clarity is respectfully requested.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the compounds which are meant to be used as immunomodulatory moieties, i.e. nitropyrrole, nitroindole, deoxyuridine.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutcherson et al. (US Patent 5,663,153).

The claims of the instant invention are drawn to a method for inducing an immune response in a mammal (human) comprising administering a compound comprising a CpG

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dinucleotide (wherein G is guanosine) and an immunomodulatory moiety wherein the compound has a greater immunostimulatory effect than the same compound lacking the immunomodulatory moiety. Administration is parenteral, oral, sublingual, transdermal, topical, intranasal, intratracheal, or intrarectal wherein dosage attains a blood level of oligonucleotide from about 0.01 micromolar to 10 micromolar and wherein the dosage is about 0.1 mg per patient per day to about 200 mg per kg body weight per day.

Hutcherson et al. disclose a method of stimulating a local immune response in cells or tissues by administering an oligonucleotide analog having at least one phosphorothioate bond to the cells or tissues wherein the phosphorothioate analogs have shown to stimulate a local immune response (an immunomodulatory moiety) in animals and humans (column 5, lines 25-30). Examples of the oligonucleotide sequences which contain the immunomodulator are SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 3, disclosed in sequence listing in columns 15-16, all of which contain the CpG dinucleotide sequence. The sequences of Hutcherson et al. induced an immune response (IL-1 $\alpha$ ) when the immunomodulator was present (P=S moiety included) and did not when there was no immunomodulator present (P=O moiety included) (column 10, table 1). The composition of Hutcherson et al. is disclosed as being capable of being administered topically (ophthalmically, vaginally, rectally, intranasally), intralesionally, orally, by inhalation, or parenterally (column 8, lines 8-23). The compositions of Hutcherson et al. enhance the humoral response at a dosage of about 3.3 mg per kg body weight per day (column 14, lines 13-15) and concentrations of approximately 1 micromolar are therapeutically effective (column 12, lines 13-15). Further it is noted that Hutcherson et al. disclose that unmethylated CpG

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dinucleotides induce B-cell activation (column 4, lines 38-40) and that the oligonucleotides may have altered sugar moieties and altered base moieties (column 6, line 63 – column 7 line 19).

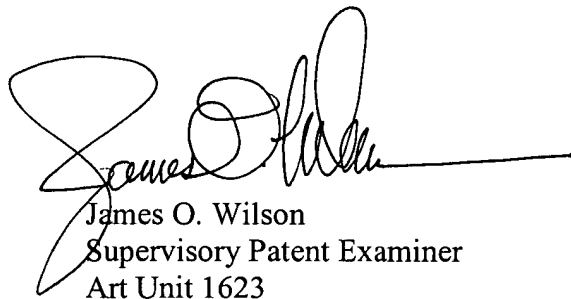
The disclosure of Hutcherson et al. is seen to clearly anticipate the methods of inducing an immune response in mammals as claimed in claims 18-22 of the instant application.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



James O. Wilson  
Supervisory Patent Examiner  
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Traviss C. McIntosh  
December 19, 2002